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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,742	11/16/2005	Manuel Sarasa Barrio	100878.56050US	9149
23911 7590 12/12/2008 CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300				
EXAMINER DUTT, ADITI				
ART UNIT		PAPER NUMBER		
1649				
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12/12/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/527,742

**Applicant(s)**

BARRIO, MANUEL SARASA

**Examiner**

Aditi Dutt

**Art Unit**

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-39 is/are pending in the application.  
4a) Of the above claim(s) 27-31 and 33-39 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 32 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SF 100)  
Paper No(s)/Mail Date 2/14/06:10/10/06  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Individual Patent Application  
6) ☒ Other: Appendices A-E

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

1. The amendment of 1 October 2008 has been entered in full.

### ***Election/Restrictions***

2. Applicant's election of Group II, claims 32, and SEQ ID NO: 2 as species of peptide in the reply filed on 1 October 2008 is acknowledged. Although Applicant did not specifically state "traversal" of restriction requirement, Applicant pointed out improper classification of claims 33-36 into Group I. Applicant argues that although the preamble of claims 33-36 recite a method of preparing an antibody, the process requires steps performed with the peptide of claim 32. Thus claims 33-36 are directed to a process of using the peptide of claim 32, thereby eligible for a rejoinder in case the product claims are allowable. Applicant requests examining the claims to avoid withdrawal and subsequent rejoinder.
3. Applicant's arguments are fully considered, however, are not found to be persuasive. Although claims 33-36 are related to the polypeptide of claim 32 by a process of use and product respectively, the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to prepare another and materially different product or (2) that the product as claimed can be used in another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptide can be used in other processes

such as therapeutic, diagnostic or in Western blot assays. Because these inventions are independent or distinct, have acquired a separate status in the art in view of their different classification and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
5. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant further requests the examination of SEQ ID NO: 3 together with the elected species SEQ ID NO:2, as both sequences are essentially the same, differing by two additional amino acids at the end of SEQ ID NO: 3.
7. Applicant's argument is considered and found to be persuasive. Therefore, the restriction requirement between SEQ ID NOs: 2 and 3 is withdrawn and SEQ ID NO: 3 is rejoined with elected SEQ ID NO: 2 in the current application.
8. **The requirement is still deemed proper and is therefore made FINAL.**
9. Claims 27-31 and 33-39, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1 October 2008.
10. Claim 32, drawn to an isolated polypeptide comprising an amino acid sequence of SEQ ID NOs: 1, 2, 3 or 4, is being considered for examination in the instant application.

***Information Disclosure Statement***

11. The information disclosure statement filed 2/14/06 has been acknowledged. However, references A1 to A3 listed in the IDS have not been submitted. The references have been added and considered in the instant Office Action.

***Oath/Declaration***

12. Mailing address of inventor

The oath is objected to because it does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

13. No reference to foreign filing

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in Spain on 12 September 2002. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claim 32 is rejected under 35 U.S.C. 102(e) as anticipated by Hartmann et al. (International Publication number WO 03/104812 A2, filed 6 June 2003, with a priority date of 6 June 2002).
15. The claim is drawn to an isolated polypeptide comprising an amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 3.
16. Hartmann et al. teach a 8 amino acid peptide that is 100% identical to the claimed polypeptide of SEQ ID NO: 2 of the instant application (see sequence alignment attached to the instant Office Action as Appendix A; also see insert below). The reference further teaches antibodies directed to the 8 amino acid

epitope that corresponds to human A $\beta$ 40 at amino acid position 33-40 (page 6, para 3; claim 6, page 12). Therefore the reference anticipates the invention.

SEQ Sequence 8 AA;

Query Match 100.0%; Score 39; DB 8; Length 8;  
Best Local Similarity 100.0%; Pred. No. 3.6e+06;  
Matches 8; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 GLMVGGVV 8  
| | | | | | | |  
Db 1 GLMVGGVV 8

17. Claim 32 is rejected under 35 U.S.C. 102(e) as anticipated by Chain et al. (International Publication number WO 2004/006861 A2, filed 16 July 2003, with a priority date of 17 July 2002).
18. Chain et al. teach a 9 amino acid peptide of SEQ ID NO: 132, that is 100% identical to the claimed polypeptide of SEQ ID NO: 2 of the instant application (see sequence alignment attached to the instant Office Action as Appendix B; also see insert below). Therefore the reference anticipates the invention.

SEQ Sequence 9 AA;

Query Match 100.0%; Score 39; DB 8; Length 9;  
Best Local Similarity 100.0%; Pred. No. 3.6e+06;  
Matches 8; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 GLMVGGVV 8  
| | | | | | | |  
Db 2 GLMVGGVV 9



19. Claim 32 is rejected under 35 U.S.C. 102(b) as anticipated by Shimohigashi et al. (Biochem Biophys Res Comm 193: 624-630, 1993).
20. Shimohigashi et al. teach a beta amyloid protein fragment peptide that is 100% identical to the claimed polypeptide of SEQ ID NO: 2 of the instant application (see sequence alignment attached to the instant Office Action as Appendix C; also see insert below; Figure 1, page 625). Therefore the reference anticipates the invention.

```
Query Match          100.0%; Score 39; DB 2; Length 42;
Best Local Similarity 100.0%; Pred. No. 0.9;
Matches      8; Conservative      0; Mismatches      0; Indels      0; Gaps      0;

Qy      1 GLMVGGVV 8
        |||
Db     33 GLMVGGVV 40
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21. Claim 32 is rejected under 35 U.S.C. 102(b) as anticipated by Seubert et al. (US Patent No. 6114133, date 5 September 2000).
22. Seubert et al. teach a 10 amino acid peptide of SEQ ID NO: 2, that is 100% identical to the claimed polypeptide of SEQ ID NO: 3 of the instant application (see sequence alignment attached to the instant Office Action as Appendix D; also see insert below). The reference further teaches polyclonal antibodies generated against A $\beta$  33-42 by conjugating SEQ ID NO: 2 with cationized BSA (col 12, lines 1-5). Therefore the reference anticipates the invention.

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Query Match          100.0%; Score 47; DB 2; Length 10;
Best Local Similarity 100.0%; Pred. No. 0.1;
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Matches 10; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 GLMVGGVVIA 10
        | | | | | | |
Db      1 GLMVGGVVIA 10
```

23. Claim 32 is rejected under 35 U.S.C. 102(a) as anticipated by Cruts et al. (International Publication number WO 02/02769 A1, dated 10 January 2002).

24. Cruts et al. teach a 10 amino acid peptide that is 100% identical to the claimed polypeptide of SEQ ID NO: 3 of the instant application (see sequence alignment attached to the instant Office Action as Appendix E; also see insert below). The reference further teaches the generation of monoclonal antibodies to this segment (page 21, lines 2-4). Therefore, the reference anticipates the invention.

```
SQ Sequence 10 AA;

Query Match      100.0%; Score 47; DB 5; Length 10;
Best Local Similarity 100.0%; Pred. No. 0.22;
Matches 10; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 GLMVGGVVIA 10
        | | | | | | |
Db      1 GLMVGGVVIA 10
```

### ***Conclusion***

25. No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571)

272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD  
5 December 2008

/Jeffrey Stucker/  
Supervisory Patent Examiner, Art Unit 1649